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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,856	11/05/2001	Thomas P. Stossel	B0801/7232	7592

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WOLF GREENFIELD & SACKS, PC
FEDERAL RESERVE PLAZA
600 ATLANTIC AVENUE
BOSTON, MA 02210-2211

EXAMINER

AFREMOVA, VERA

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/007,856

Applicant(s)

STOSSEL ET AL.

Examiner

Vera Afremova

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-4, 13, 15, 35-38, 45, 46, 48, 53-57, 67, 68 and 74-81 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 13, 15, 35-38, 45, 46, 48, 53-57, 67 and 68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1 and 74-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/29/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of claims

Claims 1 as amended and new claims 74-81 are under examination {1/29/2004}.

Claims 5-12, 14, 16-34, 39-44, 47, 49-52, 58-66 and 69-73 were canceled by applicants {4/05/2001}.

Claims 2-4, 13, 15, 35-38, 45, 46, 48, 53-57, 67 and 68 were withdrawn as directed to nonelected inventions. A complete reply should include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

Claims 1 and 74-81 re rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite and incomplete because it is drawn to the method of identifying a platelet clearance antagonist but it does not result in the identification of a molecule that is a “platelet clearance antagonist” (claim 1) or “platelet antagonist” (claim 74) or “liver macrophage receptor antagonist” (claim 77).

Claims 75, 76 and 78-80 are indefinite because they are uncertain and incomplete. It is uncertain what/whether all or some selected ligands and receptors listed in the table 1 are included in the claimed method. The claims are incomplete in the absence of recitation about what active steps are intended for identifying test molecules or else with the ligands/receptors disclosed in the table 1. The claims are indefinite because the claimed test molecule is an unidentified chemical compound that is not characterized by any structural characteristics that

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would encompass its interactions with the ligands and receptors listed in the table 1. Thus, it is uncertain what test molecule or test compound is asserted to be involved in the claimed method particularly as related to the compounds of table 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 74-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Jungi et al. {"Platelet-Leukocyte Interaction". Blood. March 1986. Vol. 67, No. 3, pages 629-636}.

Claims are directed to a method for identifying/assaying a test molecule wherein the method comprises two active steps that are step of contacting a chilled platelet with a liver macrophage in the presence and in the absence of the test molecule and step of detecting binding of the chilled platelet to the liver macrophage wherein a reduction in the binding in the presence of the test molecule relative to the binding in the absence of the test molecule indicates that the test molecule is a platelet clearance antagonist or a platelet antagonist or a liver macrophage receptor antagonist. Some claims are further drawn to ligands and receptors of platelets and macrophages.

The reference by Jungi et al. disclose a method for identifying/assaying a test molecule wherein the method comprises step of contacting platelets with monocytes in the presence and in the absence of the test molecule and step of detecting binding of the platelets to the monocytes (abstract or tables 1-4). The platelets are chilled at 4° C before binding assays (method section at

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page 629). Some cell interaction assays are performed at 0° C and, thus, platelets are chilled. Monocytes in the method of the cited reference belong to phagocyte cell lineage and mature to macrophages (page 630). The monocytes in the method of the cited reference are considered to be the same cells as the claimed "liver macrophage" in the light of applicants' definitions (page 38, line 4).

Therefore, the cited reference is considered to anticipate the claimed method because it teaches identical active steps and interactions of identical cells through binding in the presence and absence of test molecules.

The test molecule in the claimed method is any molecule having unidentified chemical structure. The test molecule is not identified by any structural characteristics that would link it to the platelet clearance antagonist or a platelet antagonist or a liver macrophage receptor antagonist. Thus, the test molecules in the cited method fall within the meaning of presently claimed terms "platelet clearance antagonist" or "platelet antagonist" or "liver macrophage receptor antagonist". Although the cited reference does not clearly indicate ligands and receptors that are within the meaning of the claimed table 1, the cited reference considers various patterns of binding/interactions between the identical cells as claimed and thus, the same ligands and receptors, if present, are inherently involved in the cited method as required for the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 74-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jungi et al. {"Platelet-Leukocyte Interaction". Blood. March 1986. Vol. 67, No. 3, pages 629-636} taken with Coller et al. {Thrombosis and Haemostasis. August 1999. 82(2), 326-336}.

Claims are directed to a method for identifying/assaying a test molecule wherein the method comprises steps of contacting a chilled platelet with a liver macrophage in the presence and in the absence of the test molecule and detecting binding of the chilled platelet to the liver macrophage wherein a reduction in the binding in the presence of the test molecule relative to the binding in the absence of the test molecule indicates that the test molecule is a platelet clearance antagonist or a platelet antagonist or a liver macrophage receptor antagonist. Some claims are further drawn to ligands and receptors of the platelets and macrophages. Some claims are further drawn to detecting phagocytosis.

The reference by Jungi et al. is relied upon as explained above for the disclosure of a method of identifying test molecules involved in the platelet-leukocyte interaction. Although it is silent about ligands and receptors involved in platelet-monocyte interactions and binding, the reference by Coller et al. teaches the ligands and receptors that are claimed and/or listed in the table 1 including alphaMbeta2 receptor, vWfR, complement C3bi and others.

The reference by Jungi et al. teaches a binding assays between platelets and monocytes including mature macrophages. The primary function of macrophage is phagocytosis. Therefore, although the cited reference does not describe a step of detecting a phagocytosis, the phagocytosis would be an obvious event in the presence or absence of at least some selected test molecule in the culture system comprising macrophage and the other cell including platelet cell.

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Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references particularly in view that no test molecule of identified chemical structure has been obtained as a result of the method of identifying test molecule as claimed. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Vera Afremova

AU 1651

April 12, 2004



VERA AFREMOVA

PATENT EXAMINER